

REMARKS**Status of the Claims**

Claims 19-23 and 26-30 are currently pending in the application and subject to a Restriction Requirement. (*See*, Office Communication of February 12, 2008, at page 2, hereinafter, "Office Communication"). Claims 24 and 25 have been cancelled without prejudice or disclaimer. New claims 29 and 30 have been added. No new matter has been added by way of the present amendments. Specifically, new claims 29 and 30 are supported by the specification at, for instance, page 2, lines 3-7 and page 4, lines 10-27. Applicants traverse the Restriction Requirement as set forth herein. Reconsideration is respectfully requested.

Unity of Invention

Claims 19-28 are pending and are subject to a Unity of Invention restriction under 35 U.S.C. §§ 121 and 372 for reciting inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1. (*See*, Office Communication, at page 2). The Examiner has separated the claims as follows:

Group I, claims 1-23 and 26, drawn to a fusion protein comprising a) a scFV, and b) cell penetrating transport peptide; a fusion protein having a medical use; and a pharmaceutical composition comprising at least one fusion protein.

Group II, claim 27, drawn to a method of making the fusion protein.

Group III, claim 28, drawn to a method of treating a disease or disorder in a human or animal comprising administering the fusion protein.

It is respectfully submitted that new claims 29 and 30 should be included in Group III.

For the purpose of examination of the present application, Applicants elect, with traverse, Group I, Claims 19-23 and 26.

Applicants believe at least Groups I and III should be rejoined since they are both related to the same special technical feature and are not drawn to patentably distinct inventions, i.e. an Applicant could not obtain a patent for directed to Group III independently of Group I.

The Examiner cites Zhao et al., *J. Immunol. Methods*, 254:137-145, 2001 (hereinafter, "Zhao et al."), for the notion that Zhao et al. teaches the presently claimed invention, and as such, there is no special technical feature in the claims which amounts to a contribution over the prior art. Applicants assert that Zhao et al. do not disclose the special technical feature of the presently claimed invention. That is, the Zhao et al. methods involve chemical attachment of MTS-sequences to proteins by NaIO₄ conjugation. In contrast, the presently claimed invention is directed to a membrane-penetrating sequence as part of a fusion protein. Thus, one of skill in the art could not combine the disclosure of Toftgard, WO 01/12655, with Zhao et al. to destroy the special technical feature of the presently claimed invention. Such a combination would yield an entirely different invention.

Furthermore, according to MPEP § 803, if the search and examination of an entire application can be made without a serious burden, the Examiner *must* examine it on the merits, even though it includes claims to independent or distinct inventions.

As such, Applicants respectfully request that the Examiner rejoins Groups I-III.

The Examiner is additionally reminded that because the present Restriction is between a product (claims 19-23 and 26) and its process of use (claims 28-30), where Applicants elect

claims directed to the product, and a product is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claims will be rejoined in accordance with the provisions of M.P.E.P. § 821.04. Such process claims that depend from or otherwise include all the limitations of the patentable product are entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Furthermore, in the event of rejoinder, Applicants understand that the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims must be fully examined for patentability according to the provisions of 37 C.F.R. § 1.104.

Additionally, according to MPEP § 1893.03(d), the Examiner is respectfully reminded that if the Examiner (1) determines that the claims lack unity of invention and (2) requires election of a single invention, when all of the claims drawn to the elected invention are allowable, the nonelected invention(s) should be considered for rejoinder. Any nonelected product claim that requires all the limitations of an allowable product claim, and any nonelected process claim that requires all the limitations of an allowable process claim, should be rejoined. (*See*, MPEP § 821.04 and § 821.04(a)). Any nonelected processes of making and/or using an allowable product should be considered for rejoinder following the practice set forth in MPEP § 821.04(b).

Reconsideration and withdrawal of the Unity of Invention Requirement of claims 19-23 and 26-30 are respectfully requested.



CONCLUSION

If the Examiner has any questions or comments, please contact Thomas J. Siepmann, Ph.D., Registration No 57,374, at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,

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